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CUMULATIVE DISTRIBUTION OF PATIENTS BY CHANGE IN FVC% PREDICTED IN THE INPULSIS® TRIALS OF NINTEDANIB IN PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS

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10.1136/thoraxjnl-2016-209333.106

Introduction The two 52-week Phase III INPULSIS® trials assessed the efficacy and safety of nintedanib in patients with IPF. In both trials, nintedanib significantly reduced the annual rate of decline in forced vital capacity (FVC) versus placebo.

Methods We assessed the cumulative distribution of patients by absolute changes from baseline to week 52 in FVC% predicted using thresholds of $\geq 0\%$, $\geq 5\%$ and $\geq 10\%$ in the individual INPULSIS® trials and pooled data. Missing data (due to death, loss to follow-up, or censoring before week 52) were imputed using the worst decline from baseline at week 52 observed in all patients with available data regardless of treatment.

Results 1061 patients were treated in the INPULSIS® trials (n = 638 nintedanib; n = 423 placebo). In INPULSIS®-1, a

smaller proportion of patients treated with nintedanib than placebo had any decline in FVC% predicted (absolute decline in $FVC \geq 0\%$ predicted) (71% versus 82%; $p = 0.002$), an absolute decline in $FVC \geq 5\%$ predicted (47% versus 62%; $p = 0.001$) and an absolute decline in $FVC \geq 10\%$ predicted (29% versus 43%; $p < 0.001$) from baseline to week 52 based on the cumulative distribution of patients. In INPULSIS®-2, a smaller proportion of patients treated with nintedanib than placebo had any decline in FVC% predicted (70% versus 88%; $p < 0.001$), an absolute decline in $FVC \geq 5\%$ predicted (47% versus 61%; $p = 0.001$) and an absolute decline in $FVC \geq 10\%$ predicted (30% versus 36%; $p = 0.18$) from baseline to week 52. In pooled data, the proportions of patients treated with nintedanib and placebo, respectively, who had any decline in $FVC \geq 0\%$ predicted, an absolute decline in $FVC \geq 5\%$ predicted and an absolute decline in $FVC \geq 10\%$ predicted were 70% versus 85% ($p < 0.001$), 47% versus 61% ($p < 0.001$) and 30% versus 39% ($p < 0.001$) (Figure). The proportion of patients with no decline or an improvement in FVC% predicted were 30% in the nintedanib group versus 15% in the placebo group.

Conclusion In the INPULSIS® trials, a higher proportion of patients with IPF treated with nintedanib than placebo had no decline or an improvement in FVC. Smaller proportions of patients had absolute declines in $\geq 5\%$ and $\geq 10\%$ predicted over 52 weeks.